

## **REMARKS**

### *Claim Objections*

Claims 1-38 were pending prior to this Response. The Examiner asserts that Claims 3-9, 12, 14, 15, 18, 19, 36 and 37 are directed to non-statutory subject matter as use claims. In this Response, applicants amend Claims 3-9, 12, 14, 15 and 18 so that they are method claims. Applicants respectfully assert that the amendments address the Examiner's objection with respect to Claims 9, 12, 14, 15 and 18. Applicants will amend Claims 19, 36, and 37 so that they are method claims once the Examiner considers applicants' traversal of the Restriction Requirement and the supporting arguments, below, and withdraws the Restriction Requirement.

The Examiner asserts that Claims 12, 14-18 and 27-35 are improper multiple dependent claims because each of these claims depends on multiple-dependent claims. Applicants amend Claims 12 and 14-18 to correct the informality. Applicants assert that the amendments overcome the objection with respect to Claims 12 and 14-18. Applicants will amend Claims 27-35 to correct the informality once the Examiner considers applicants' traversal of the Restriction Requirement and the supporting arguments, below, and withdraws the Restriction Requirement.

### *Claim Amendments*

In addition to addressing the above claim objections, applicants also amend Claims 1-18 to correct informalities, spelling, and for clarity. The amendments do not introduce any new matter. Currently amended Claims 1-18 are based on original Claims 1-18. If any of the amendments are defective, applicants request the Examiner to enter any defective amendments that are clear from the context as provided in MPEP 714(II)(G).

*Restriction*

In the Restriction Requirement mailed September 27, 2006, the Examiner requires applicants to elect, one of the following five groups of claims.

- I. Claims 1-8 and 11-18, drawn to a method for detecting cancer-associated anti-tumor autoantibodies using a tumor marker protein based-immunoassay where the presence of the autoantibody can be used to detect or diagnose a cancer, monitor the progress of a cancer, detect or screen a cancer in an asymptomatic patient, monitor the response to an anti-cancer treatment, and detect the recurrence of a cancer.
- II. Claims 9 and 10, drawn to a method of screening an anti-cancer vaccine and a method of monitoring an immune response to an anti-cancer vaccine comprising an immunoassay for the detection of cancer-associated anti-tumor autoantibodies.
- III. Claims 20-31, drawn to methods for preparing a tumor marker protein.
- IV. Claims 32-35, drawn to a preparation comprising a tumor marker protein and a kit for an immunoassay comprising a tumor marker protein immobilized to a solid support.
- V. Claim 38, drawn to a method for calibrating an assay for measurement or detection of a tumor marker protein.

Claims 19, 36 and 37 are withdrawn from Restriction as unclear.

Applicants elect Group I, Claims 1-8 and 11-18, with traversal. Applicants traverse the Restriction Requirement as improper for at least the following reasons

As provided in MPEP 1893.03, for an international application that enters the national stage, unity of invention is determined in accordance with 37 C.F.R 1.475, which essentially lays out the requirements of PCT Rule 13. The present application is a US National Stage Application of International Application No. PCT/GB03/0495. Applicants bring to the Examiner's attention that **International Preliminary Examination**

**Report in the above international application, completed on November 1, 2005, does not indicate lack of unity under PCT Rule 13.** The claims that were pending in the present application prior to the present Response were the same claims as those examined in International Preliminary Examination Report. Accordingly, applicants respectfully assert that the claims do not lack unity under PCT Rule 13 and 37 C.F.R 1.475. Applicants request withdrawal of the Restriction Requirement for at least this reason and examination of all pending claims on the merits.

Furthermore, applicants assert that Claims 9 and 10, identified as Group II by the Examiner, do not lack unity with Group I, Claims 1-8 and 11-18, at least because Claims 9 and 10 recite all the same method steps as Claim 1. Claim 9 is dependent on Claim 1 and incorporates all of its limitations. Accordingly, applicants traverse the Restriction Requirement at least between Groups I and II, and request the Examiner to join of Groups I and II and to examine at least Claims 1-18.

*Election of Species*

If one of Groups I, II, or III are elected, for prosecution purposes only if no generic claim finally held to be allowable, the Examiner requires applicants to elect one of the following species:

- A. MUC1
- B. MUC16
- C. c-myc
- D. c-erbB2
- E. p53
- F. ras
- G. BRCA1
- H. BRCA2
- I. APC
- J. PSA
- K. CEA
- L. CA 19.9

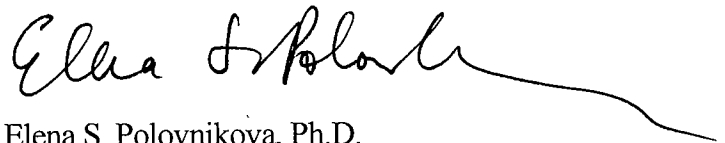
Applicants elect species F, ras, **for prosecution purposes only if no generic claim finally held to be allowable.** If the claims as directed to the elected species are found allowable, applicants request examination and allowance of the generic claims.

### CONCLUSION

The foregoing is submitted as a full and complete response to the Restriction Requirement mailed September 27, 2006. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to Elena S. Polovnikova at (404) 815-6102 or to Jamie L. Greene at (404) 745-2473 is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Elena S. Polovnikova', followed by a long horizontal line extending to the right.

By: Elena S. Polovnikova, Ph.D.  
Patent Agent  
Reg. No. 52,130

KILPATRICK STOCKTON LLP  
1100 Peachtree Street, Suite 2800  
Atlanta, GA 30309-4530  
Phone: (404) 815-6500  
Facsimile: (404) 815-6555  
Docket No. 49409-0050 (315804)